

## REMARKS

Claims 26-39 are pending.

Claims 26-39 stand rejected.

Claims 26, 27, 29, 31 and 32 have been amended.

Claim 40 has been added.

Claims 26-40 are submitted herein for consideration.

No new matter has been added.

In section 2 of the Office Action, the Examiner has rejected claims 26-39 under 35 U.S.C. § 112 for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. In particular the Examiner has noted some minor objections to claims 26, 27, 29, 31 and 32.

Applicants have amended claims 26, 27, 29 and 31 according to the Examiner's suggestions and respectfully request that the rejection of these claims be withdrawn. Regarding claim 32 the term, "group consisting of the analogue of tiroxine, triiodotiracetic acid" has been amended to read, "consisting of triiodotiracetic acid, and any tiroxine analogs."

Applicants assert that the term "analog" is well known in the art of pharmaceuticals. Thus, contrary to the Examiner's assertion, the term analogs, does not render the claim indefinite. Rather, one skilled in the art of the pharmaceuticals would readily recognize this element to be limited to the inclusion of either triiodotiracetic acid or any other tiroxine analog. Such tiroxine analogs include any pharmacological analog derivative from tiroxine. As such, Applicant's respectfully request that the rejection of

this claim on this ground be withdrawn.

In section 3 of the Office Action the Examiner has rejected claims 26, 29, 30, 33 and 36-37 as being unpatentable over Marquie et al. (Life Sciences, 1998; 63(1):65-67), Pentikainen et al. (Annals of Medicine, 1990;22:307-312), and Poupon et al. (Hepatology, 1993;17(4):577-582 in view of Spasmo-Canulase® Bitlab ® package insert (July 1989). Claims 27, 28, 31-32, 34-35 and 38-39 are rejected under 35 U.S.C. § 103 as being unpatentable over Marquie, Pentikainen, Poupon, and Spasmo-canulase Bittab, further in view of Hydrocotyle (A Modern Herbal Home Page, 1995), Kang et al. (Archives of Physiology and Biochemistry, 1997;105(6):603-607), Pondimin monograph (PDR, 199, page 2066-2067 and Keown et al. (WO 95/11034).

Applicants respectfully disagree with the Examiner's contentions and submit the following remarks in response. Applicants submit herewith a Declaration under 37 CFR 1.132 to accompany these remarks.

The present invention as claimed in claim 26 is directed to a method for treating a patient suffering from the side-effects of a ketogenic diet comprised of administering a composition of a plurality of agents that produces a synergistic effect of reducing the concentration of a plurality of internal body chemicals, comprised of a hypocholesterolemic agent, selected from the group consisting of benfluorex and ursodesoxycolic acid. A hypotriglyceride agent, benfluorex and a lipasic and proteasic agent, pancreatine IX F.U. are also administered. The administered composition further comprises a hypoglycemic agent, metformine and a hydrocoleretic agent selected from the group consisting of Na dehydrocloatye and ursodesoxycolic acid.

The present invention in claim 27 further claims the addition of a hypouricemic

agent, a radical scavenger, a sympatholytic agent, a sympathicomimetic agent and a vitamin. Claim 28 further claims the additional administration of any one of a sedative-ansiloytic agent, an anorectic agent or a lipolytic agent.

The present invention in claim 29, further claims the specific weight, with respect to the total composition weight, for the administration of the benfluorex, pancreatine, metformine and Na dehydrocloate. Claim 30 further claims the specific weight, with respect to the total composition weight, for the administration of ursodesoxycolic acid.

The present invention as claimed in claim 31 further claims the specific weight, with respect to the total composition weight, for the administration of the components of the composition as claimed in claim 27. The present invention as claimed in claim 32 further claims the specific weight, with respect to the total composition weight, for the administration of the components of the composition as claimed in claim 28. Claims 33-39 further claims the administration of the composition to the patient in daily doses of 7g to 23g per day.

To this end, the present invention as claimed is directed to a method for treating the side effects of a ketogenic-diet. Ketogenic diets are typically administered to obese patients in order to reduce weight. In doing so, carbohydrates are nearly or entirely removed from the diet and replaced with non-carbohydrate containing foods, having high protein and fat content.

In administering this diet, there are several side effects that occur as a result in typical patients. These side effects may include hypercholesterolemia, hypertryglyceridemia, hyperuricemia, hyperglycemia, hepatic-pancreatic alterations and mental disorders which manifest as higher concentrations of certain bodily chemicals.

The present invention looks to treat these conditions collectively by administering a single compound having a plurality of active agents, that helps to control all of these side-effects simultaneously. To this end, it has been found that the compound claimed in the present invention, was effective at stabilizing/lowering a number of internal bodily chemicals of such elements as cholesterol, tryglicerides, glicemia, uric acid, transaminases, the raised levels of which are associated with ketogenic diet side effects. In addition, internal fibrinogen levels were also found to be reduced by the administration of the compound of the present invention.

Thus, the present invention has found a favorable synergistic effect in treating a range of internal factors, all of which are related to the side effects of a ketogenic diet, by the administration of the claimed compound. Furthermore, this synergistic effect between the plurality of active agents has been realized when administered in the ratios as claimed. The final result of this product is the treating of a wide range of effects, collectively caused/exacerbated by a ketogenic diet, through the administration of a single compound.

#### Regarding Independent Claim 26

Turning to the prior art, namely Marquie, teaches the use of benfluorex to decrease glucose intolerance, hyperinsulinemia, hypertryglyceridemia, hypercholesterolemia and plasma LDL- and VLDL-cholesterol as set forth in the abstract. The Marquie reference deals only with the use of benfluorex alone in treating the researched factors, as shown in page 71, indicating that benfluorex was effective after about 3 months in reducing certain internal levels of harmful elements.

The Pentikain reference teaches the use of metformin to lower cholesterol in

patients. It is noted in the second sentence of the discussion on page 311, that metformin does not, "significantly affect HDL-cholesterol and triglyceride concentrations in combined hyperlipidemia."

The Poupon reference teaches a study showing the cholesterol lowering effect of ursodeoxycholic acid. In the abstract, it is noted that "[n]o significant change occurred in total triglyceride or total phospholipid levels."

The spasmo-canalase reference teaches the administration of Na dehydrocholate for treating abdominal cramps, caused by flatulence.

None of the cited prior art references either alone or in combination, teach or suggest the present invention as claimed. As discussed above, the administration of the combined agents of the present invention provide a synergistic effect, simultaneously reducing levels of cholesterol, triglycerides, glycemia, uric acid, transaminase and fibrinogen, all within two months of treatment. See page 4, paragraph 4 of the attached Declaration.

On the contrary the cited references, merely state that a few of the agents, independently maintaining differing individual effects on levels of certain body chemicals as outlined above. However, in none of the four references cited is it suggested that the agents be combined into a single compound having synergistic effect of reducing the concentration of a plurality of bodily chemicals.

Furthermore, it is noted that page 71 of the Marquie reference noted a 3 month period before it became effective, whereas page 4 of the attached Declaration notes that the effective treatment using the present invention obtains results in 2 months. This earlier and more effective result indicates a synergistic effect of the administration of a

combination of agents employed in the present invention that is not suggested in any of the cited references.

As such, there is no teaching or suggestion, in any one of the cited prior art, either alone or in combination, that teach or suggest the present invention as claimed. For example, none of the cited prior art references, teach or suggest administering a composition of a plurality of agents that produces a synergistic effect of reducing the concentration of a plurality of internal body chemicals, where the composition is comprised of, a hypocholesterolemic agent, a hypotriglyceride agent, a lipasic and proteasic agent, a hypoglycemic agent, wherein said hypoglycemic agent is metformine; and a hydrocoleretic agent.

#### Regarding Claim 27

The Hydrocotyle reference, teaches that hydrocotyle asiatica acts as a mild stimulant. The Kang reference teaches the use of selenium to decrease NOS (Nitric Oxide Synthase) activity (page 604, second sentence of discussion). Neither reference teaches its combination with other components to reduce the effect of a ketogenic diet.

The Pondimin reference teaches that fenfluramine is a sympathomimetic amine (anorectic) which acts primarily as an appetite suppressant. Although it mentions that blood glucose levels were reduced, it indicates that the mechanism of operation is not clear. Furthermore, it contains no indication of synergistic effect when used in combination with other compounds.

The Keown reference teaches a weight reduction composition that produces significant weight over a period of time and is safe, lacking the disadvantage of protein loss. The composition comprises two substances, a sympathomimetic agent and a salt or

chelate mineral. The two substances provide an anorectic effect and normalize insulin level in the blood (Page 8, lines 27-28).

None of the cited prior art references either alone or in combination, teach or suggest the present invention as claimed. As discussed above, with regard to claim 26 the administration of the combined agents of the present invention provides a synergistic effect, simultaneously reducing levels of cholesterol, triglycerides, glicema, uric acid, transaminase and fibrinogen, all within two months of treatment.

None of the cited references contain a suggestion to combine a hypouricemic agent, a radical scavenger agent, a sympatholytic agent, a sympathicomimetic agent, and at least one vitamin, to the composition administered in claim 26. This combination, claimed in the present invention, has produced a synergistic effect to collectively lower the concentration of a plurality of internal body chemicals, combating the side effects common to ketogenic diets.

As such there is no teaching or suggestion in any one of the cited references, either alone or in combination, that teach or suggest the present invention as claimed. For example, there is no teaching or suggestions in the cited prior art for the administration of a hypouricemic agent, a radical scavenger agent, a sympatholytic agent, a sympathicomimetic agent, and at least one vitamin.

#### Regarding Claims 28-39

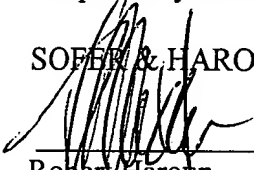
The claims ultimately depend from claims 26 and 27, and thus should be deemed allowable for the same reasons.

Furthermore, the Examiner' has simply stated in the Office Action that the optimization of result effect parameters (ie. dosage range, and dosing regiments) is

obvious as being within the skill of the artisan. However, Applicants assert that the ratios of weight with respect to the overall weight as proscribed in claims 29-32 amount to more than mere dosage, indicating relative amounts of agents within a product. As described in the Declaration, the combination of the various agents in these designated ratios has produced a synergistic effect not taught in the cited prior art. Furthermore, these ratios could not be taught or suggested in the prior art as the prior art references all relate to single compounds and thus do not teach or suggest ratios of compounds with respect to one another.

As such, in view of the above amendments and remarks, Applicants request that the rejection to the claims 26-39 be withdrawn and that new claims 40 not be subject to rejection and respectfully submit that the present invention as claimed is now in condition for allowance, the earliest possible notice of which is earnestly solicited. If the Examiner feels that a telephone interview would advance the prosecution of this application they are invited to contact the undersigned at the number listed below.

Dated:  
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